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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/892,340 | 06/27/2001 | Robert A. Rousseau | ETH-1507 | 3554 |
| 27614 | 7590 | 08/22/2005 | EXAMINER | |
| MCCARTER & ENGLISH, LLP FOUR GATEWAY CENTER 100 MULBERRY STREET NEWARK, NJ 07102 | | | PRONE, CHRISTOPHER D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,340

Applicant(s)

ROUSSEAU, ROBERT A.

Examiner

Christopher D. Prone

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 4, 5, 6, 11, 13, 14, 15, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gianturco (EP 0544485 B1).

With regards to Figure 10 and 12 Gianturco discloses a biocompatible circular prosthetic mesh system adapted for implantation into a body comprising a flexible mesh layer, the mesh layer having a generally flat shape when it is in a first condition (Fig. 10) and a generally collapsed shaped when in its second condition (Fig. 12). The mesh layer has a ridge formed therein that is irremovably therewith and projecting therefrom in a direction substantially perpendicular to said mesh layer when said mesh layer is in said first flat condition. The ridge is formed of a thin piece of Nitinol and is therefore sized and capable of facilitating movement from it's collapsed configuration to an expanded flat configuration after being implanted in the body (11:1-12:5). The patch may be used to repair a hernia (12:6-13). The Nitinol ridge undergoes a thermoforming process to set the ring to a predetermined configuration (11:1-17). Figure 10 discloses a plurality of ridges 115 in ring/loop configurations about the circular mesh system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gianturco in view of Bendavid et al (USPN 4,769,038).

Gianturco as discussed above, discloses the prosthetic mesh system as claimed. Gianturco however fails to disclose another mesh layer connecting to said mesh layer. With reference to Figure 1 Bendavid teaches a prosthetic mesh system comprising biocompatible, flexible mesh layers 12,16 and another mesh layer 14 connected to said mesh layers 12,16 by connecting means 18 to provide a prosthetic mesh with an arrangement of layers that enable the herniated muscles to be reconstructed with the layers of the prosthesis in a manner which does not stretch the musculature. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the prosthetic mesh as disclosed by Gianturco by incorporating an additional mesh layer as taught by Bendavid in order to provide a prosthesis with a structure that reduces the stretching of the musculature and minimizes the risk for re-injuring the herniated muscle.

Claims 8, 9, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianturco as modified by Bendavid and further in view of Gonzalez (WO 97/22310).

As discussed above, Gianturco as modified by Bendavid, discloses the prosthetic mesh assembly as claimed. While Gianturco suggests that any shape prosthetic mesh may be used (13:5+), Gianturco as modified by Bendavid fails to disclose the particular shape of the mesh as claimed by the applicant. Gonzalez teaches a biocompatible, flexible prosthetic mesh assembly in a circular configuration with a ridge formed concentrically about the perimeter of the mesh to provide self-unfolding device that simplifies surgical procedures (abstract). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the prosthetic mesh as disclosed by Gianturco by forming the ridge concentrically about the perimeter of the device to provide a self-unfolding hernia patch that reduces the need of stitches and/or staples and reduces the difficulty of implantation.

Response to Arguments

Applicant's arguments filed 5/27/05 have been fully considered but they are not persuasive.

Applicant argues that Gianturco does not disclose that his mesh layer in the location of the ridge has rigidity, which is not greater than the rigidity of the rest of the mesh layer. The applicant's argument is wrong because it is broader than what is stated

in the claim. Claim 1 reads: the mesh layer located at the ridge, (not the stiffener) has rigidity not greater than that of the rest of the mesh layer. Since the mesh layer is the same material throughout, it is inherent that the rigidity of the mesh located at the ridge is equal to that of the rest of the mesh layer. Regardless of the stiffener the properties of the mesh layer are constant throughout.

Applicant further argues that Gianturco does not disclose a monolithically formed ridge. According to Merriam Webster's dictionary monolithic is defined as exhibiting or characterized by often rigidly fixed uniformly. In the broadest interpretation the mesh of Gianturco is uniformly and rigidly fixed around the stiffener, which is clearly shown in figures 10 and 11 of Gianturco.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher D Prone
Examiner
Art Unit 3738


CDP


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